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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,583	01/24/2002	Jack L. Strominger	24655-017	4704

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EXAMINER	
BUNNER, BRIDGET E	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/056,583	STROMINGER ET AL.	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-61* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claim 1, drawn to a composition comprising a peptide with an amino acid sequence having 2 tyrosine residues and a lysine residue, classified in class 530, subclass 350.

2. Claims 2-8, drawn to a composition comprising a peptide with an amino acid sequence having at least a tyrosine residue, a valine residue, and a lysine residue, classified in class 530, subclass 350.

3. Claims 9-27, 59-60, drawn to a composition comprising a synthetic peptide wherein the peptide has an amino acid sequence having a greater inhibitory activity for binding to the antigen binding groove of an MHC class II HLA-DR2 protein, classified in class 530, subclass 350.

4-26. Claims 28-32, 61, drawn to a composition comprising one synthetic peptide having an amino acid sequence selected from the group consisting of SEQ ID NOs: 60, 63-67, 83-99, classified in class 530, subclass 300.

27-49. Claims 33, 49-54, 57-58, drawn to a method for reducing demyelination of cells in a subject by administering one of the amino acid sequences of SEQ ID NOs: 60, 63-67, 83-99, classified in class 514, subclass 12.

50. Claims 34, 36, and 38-45, drawn to a method for obtaining a synthetic peptide having inhibitory activity for binding of an immunodominant epitope of MS, classified in class 435, subclass 4.

51. Claims 35-36, 38-45, drawn to a method for obtaining a synthetic peptide having inhibitory activity for proliferation of cells of a T cell line, classified in class 435, subclass 4.

52. Claim 37, drawn to a method of measuring the ability of peptides to inhibit presentation of the reference compound to HLA restricted T cells, classified in class 435, subclass 4.

53. Claims 46-48, drawn to a method for measuring an amount of proliferation of a DR2-restricted cell line of T cells exposed to the complex of the peptide with the MHC class II protein, classified in class 435, subclass 4.

54-76. Claims 55-56, drawn to a method of formulating a composition, classified in class 530, subclass 333.

The inventions are distinct, each from the other because of the following reasons:

The compositions and peptides of Groups 1-26 are patentably distinct inventions for the following reasons. Each of the peptides of Groups 1-26 is composed of different amino acids and is a structurally distinct molecule.

Furthermore, searching the inventions of Groups 1-26 together would impose a serious search burden. In the instant case, the search of the polypeptides is not coextensive. There is a search burden in the non-patent literature, as well as an extensive analysis of the art retrieved in a sequence search. As such, it would be burdensome to search the inventions of 1-26 together.

Inventions 27-76 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method of reducing demyelination of cells in a subject by administering an amino acid sequence (Groups 27-49), the method of obtaining a synthetic peptide having inhibitory activity for binding of an immunodominant epitope of MS (Group 50), the method of obtaining a synthetic peptide having inhibitory activity for proliferation of cells of a T cell line (Group 51), the method of measuring the ability of peptides to inhibit presentation of the reference compound to HLA restricted T cells (Group 51), the method of measuring an amount of proliferation of a DR2-restricted cell line of T cells exposed to the complex of the peptide with the MHC class II protein (Group 53), and the method of formulating a composition (Groups 54-76) are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Therefore, each method is divergent in materials and steps. For these reasons the Inventions 27-76 are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups 27-76 have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups 27-76 together.

Inventions 4-26 and 27-49 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the claimed peptide product of Groups 27-49 can used in materially different methods, such as in diagnostic assays or to generate antibodies.

Searching the inventions of Groups 4-26 and 27-49 together would impose serious search burden. The inventions of Groups 4-26 and 27-49 have a separate search status in the art as shown by their different classifications. Moreover, in the instant case, the search for the peptide composition and a method of reducing demyelination of cells in a subject by administering an amino acid sequence are not coextensive. Groups 4-26 encompass molecules which are claimed in terms of compositions consisting of a specific amino acid sequence, which are not required for the search of Groups 27-49. In contrast, the search for Groups 27-49 would require a text search for the method of reducing demyelination of cells in a subject by administering an amino acid sequence in addition to search of a specific polypeptide sequence. Moreover, even if the polypeptide product were known, the method of reducing demyelination of cells in a subject which uses the product may be novel and unobvious in view of the preamble or active steps.

Inventions 4-26 and 54-76 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case, the claimed peptide product of Groups 27-49 can used in materially different methods, such as in diagnostic assays or to generate antibodies.

Searching the inventions of Groups 4-26 and 54-76 together would impose serious search burden. The inventions of Groups 4-26 and 54-76 have a separate search status in the art as shown by their different classifications. Moreover, in the instant case, the search for the peptide composition and a method of formulating a composition are not coextensive. Groups 4-26 encompass molecules which are claimed in terms of compositions consisting of a specific amino acid sequence, which are not required for the search of Groups 54-76. In contrast, the search for Groups 54-76 would require a text search for the method of formulating a composition in addition to search of a specific polypeptide sequence. Moreover, even if the polypeptide product were known, the method of formulating a composition may be novel and unobvious in view of the preamble or active steps.

Inventions 1-3 and 27-76 are unrelated because the products of Groups I-III are not used or otherwise involved in the processes of Groups 27-76.

Inventions 4-26 and 50-53 are unrelated because the products of Groups 4-26 are not used or otherwise involved in the processes of Groups 50-53.

2. This application contains claims directed to the following patentably distinct species of the claimed invention:

A composition comprising a peptide with an amino acid sequence further comprising an additional therapeutic agent wherein the additional therapeutic agent is:

a. an interferon

b. a random heteropolymer of amino acids

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-2 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. This application contains claims directed to the following patentably distinct species of the claimed invention:

A composition comprising a synthetic peptide further comprising at least one non-naturally occurring amino acid wherein the non-naturally occurring amino acid is a substitution with the pepidomimetic compound:

c. Tic

d. Thiq

e. Disc

f. C(Prm)

g. C(Acm)

h. C(Ace)

i. MePhg

j. Nva

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 9 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. This application contains claims directed to the following patentably distinct species of the claimed invention:

A composition comprising a synthetic peptide having an amino acid sequence further comprising a substitution of an alanine or lysine at position P4 by an amino acid selected from the group consisting of:

k. tyrosine

l. phenylalanine

m. methionine

n. valine

o. isoleucine

p. leucine

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 28 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. This application contains claims directed to the following patentably distinct species of the claimed invention:

A method for obtaining a synthetic peptide comprising selecting the amino acids contacting the P1 and P4 pockets from the hydrophobic amino acids group consisting of:

q. tyrosine

r. valine

s. phenylalanine

t. methionine

u. isoleucine

v. leucine

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 34-35 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. This application contains claims directed to the following patentably distinct species of the claimed invention:

A method of treating a subject having a demyelinating condition wherein the demyelinating condition is selected from the group consisting of:

w. post-viral encephalomyelitis

x. a post-vaccine demyelinating condition

y. a multiple sclerosis

z. and a side effect of administering an anti-TNF agent

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 49 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102,

103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

If Applicant selects Invention 1 or 2, one species from the therapeutic agent group must be chosen to be considered fully responsive.

If Applicant selects Invention 3, one species from the pepidomimetic group must be chosen to be considered fully responsive.

If Applicant selects one from Inventions 4-26, one species from the P4 substitution group must be chosen to be considered fully responsive.

If Applicant selects one from Inventions 50-51, one species from the hydrophobic amino acid group must be chosen to be considered fully responsive.

If Applicant selects one from Inventions 27-49, one species from the demyelinating condition group must be chosen to be considered fully responsive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BEB
Art Unit 1647
30 September 2004

Bridget E. Bunner